REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the foregoing arguments is respectfully requested.

Claims 7-10, 12-14 and 16 are pending and under consideration. Claims 7-10, 12-14 and 16 have been amended. Claims 7, 10, 12, 13 and 16 have been amended to require 85% identity with a sequence selected from the group consisting of SEQ ID NOS: 41-49. Support for the amendment can be found in the specification at page 13, lines 1-7. Claims 8, 9 and 14 have been reworded in order to place the claims in better condition for allowance. No new matter has been added as a result of these amendments.

Objection to the Disclosure Under 37 C.F.R § 821

The disclosure is objected to because the specification and claims are not in compliance with 37 C.F.R § 821 which requires the use of the sequence designator, "SEQ ID NO:". The specification and claims have been amended to include the designator "SEQ ID NO:" language as required. No new matter has been added. Applicants respectfully request the Examiner to approve the enclosed substitute specification which incorporates these changes and withdraw the objection under 37 C.F.R § 821.

Additionally, the specification has been amended to correct minor typographical errors and update the priority data under the first paragraph of page 1 of the specification entitled "Cross-Reference to Related Application." No new matter has been added.

Rejection of Claims 13 and 14 Under 35 U.S.C. § 112, First Paragraph

Claims 13 and 14 are rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement. The Examiner asserts that claims 13 and 14 are drawn to a method for treating an individual and states that "In common parlance, 'individual' refers to a person, a human, and while the word is not defined in the claims or in the specification, 'human' is identified along with animals such as a mouse, a rabbit or a goat as subjects for producing antibodies although the animals are preferred (page 44, lines 3-6)." The Examiner further asserts that although at page 33, lines 30-33 and in Example 13 of the specification, animals are mentioned in connection to antibodies raised for therapy, administration of such to a human is not described. Furthermore, the Examiner asserts that the specification fails to establish any useful result of the claimed methods of treating humans to generate antibodies. The Examiner states that on the contrary, antibodies for the detection of CS193 protein which provides a useful marker of GI tract diseases, are described in the specification. Finally, the Examiner asserts that the specification fails to describe treatment protocols such as CS193 protein dosages, routes of administration, duration of therapy, etc. For these reasons, the Examiner contends that Applicants were not in possession of the methods of treating humans with CS193 protein to produce antibodies thereto at the time the invention was made. Applicants respectfully traverse this rejection.

Applicants have amended claims 13 and 14 to delete the "CS193" language in order to place the claims in better form. This amendment is not to be construed in any way as to Applicants' concurrence to the Examiner's position indicated above.

Applicants respectfully submit that the Examiner is not correct in stating that claims 13 and 14 are drawn to a method for treating an individual. Claims 13 and 14 are drawn to a method for producing antibodies, although the method requires administering to an individual a plasmid or an isolated immunogenic

polypeptide or fragment thereof in an amount sufficient to elicit an immune response.

Applicants respectfully submit that the Examiner is not correct in stating that "individual" is not defined in the specification. At page 17, lines 1-3, "individual" is expressly defined as "vertebrates, particularly members of the mammalian species and includes, but is not limited to, domestic animals, sports animals, primates and humans; more particularly, the term refers to humans" (emphasis added). While animals other than a human such as a mouse, a rabbit or a goat are described as subjects for producing antibodies at page 44, lines 3-6 and Example 13 of the specification, such animals are described as preferred embodiments to the invention and indicated as "preferred" as correctly pointed out by the Examiner and explicitly stated in the specification.

While the Examiner asserts that the specification fails to establish any useful result of the claimed methods of treating humans to generate antibodies, the Examiner states that on the contrary, antibodies for the detection of CS193 protein which provides a useful marker of GI tract diseases, are described in the specification. As stated above, the claims are drawn to a method for producing antibodies in an individual instead of a method for treating an individual. Nevertheless, Applicants point out that one may raise antibodies in an individual, may it be an animal or a human, for extraction and use the antibodies for a treatment as well. The significance and benefits of extraction of an individual's, i.e., a human's, cells such as in the case of blood transfusion, organ transplants, and bone marrow transplants are well documented. The Examiner further argues that the specification fails to describe treatment protocols such as CS193 protein dosages, routes of administration, duration of therapy, etc. Applicants assert that the dosage and routes of administration or duration of therapy would have been determined by one of ordinary skill in the art via undue experimentation.

For these reasons, Applicants contend that they are in possession of the methods of producing antibodies in individuals such as humans by administering a plasmid or immunogenic polypeptide, as claimed, at the time the invention was

made. Applicants respectfully request withdrawal of the rejection of claims 13 and 14 under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement.

Rejection of Claims 10 and 14 Under 35 U.S.C. § 112, Second Paragraph

Claims 10 and 14 are rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner contends that the claims are indefinite because the phrase "epitope derived from an amino acid sequence or a polypeptide" (emphasis added) is not defined in the claims or in the specification. Applicants respectfully traverse this rejection.

Epitope is a well-defined term in the art. Molecular Biology (4th Ed., Lodish et al., W. H. Freeman and Company, 2000) defines epitope as the part of an antigen molecule that binds to an antibody, also called an antigenic determinant. Immunobiology (5th Ed., Janeway et al., Garland Publishing, 2001) defines epitope as a site on an antigen recognized by an antibody or an antigen receptor. At page 16, lines 6-11, the specification explicitly states "As used herein, 'epitope' means an antigenic determinant of a polypeptide or protein. Conceivably, an epitope can comprise three amino acids in a spatial conformation which is unique to the epitope."

Applicants submit that from what is defined in the specification and in the art, the phrase "epitope derived from an amino acid sequence" is definite as it means a site on an amino acid sequence or antigen which is recognized by an antibody or an antigen receptor.

However, in an effort to expedite prosecution, Applicants have amended the claims to delete the "CS193 epitope" language from all of the claims. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 10 and 14 under 35 U.S.C. § 112, Second Paragraph.

Rejection of Claims 7-10, 12 and 16 Under 35 U.S.C. § 102(b)

Claims 7-10, 12 and 16 are rejected under 35 U.S.C. § 102(b), as being anticipated by Cunningham et al. (*J. Biol. Chem.* (1995) 270(52):31016-31026). Specifically, Cunningham et al. disclose a polypeptide having 82% identity to a sequence designated SEQ ID NO: 43 of the invention. Applicants have amended claims 7-10, 12 and 16 to require at least 85% identity of a sequence selected from the group consisting of SEQ ID NO: 41-49. Accordingly, Applicants submit that the amendment overcomes the rejection and Applicants respectfully request the withdrawal of the rejection of claims 7-10, 12 and 16 under 35 U.S.C. § 102(b), as being anticipated by Cunningham et al.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101, 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,
Billing-Medel et al.

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